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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,814	07/24/2001	Vasily A. Topolkaev	11302-1230	6279

7590 07/22/2004

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EXAMINER

MCCLENDON, SANZA L

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,814

Applicant(s)

TOPOLKARAEV ET AL.

Examiner

Sanza L McClendon

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/21/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if applicant is intending the draw or stretch ratio to be a machined direction drawn, longitudinal direction drawn or a transverse direction drawn ratio. Clarification if requested.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
2. Claims 1-10, 14, and 16-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (5,782,787).

Webster et al teaches moisture-responsive absorbent wound dressings. Said wound dressings comprise a polymer foam layer and a moisture permeable layer (backing layer), wherein said foam layer comprises a plurality of discrete zones on at least one surface (surface closest to wound). When said dressing is placed against a wound surface, exudate is absorbed by the first surface of the polymeric foam layer between

Art Unit: 1711

the zones and the foam layer swells. The swellability on contact with water of the polymeric zone material is less than that of the foam layer the zones move apart to expose more of the polymeric foam layer. The foam layer swells, such that the more exudate the more the foam swells, the less the exudate the more the foam will contract into its original position.

Said foam layer comprises a conformable hydrophilic synthetic polymer, which is capable of adsorbing wound exudates. Said discrete zones comprise blend of different polymers. Said backing layer (moisture vapor permeable layer) will be coextensive with the foam layer and aides as a control mechanism for the escape of moisture vapor from the foam layer. This appears to anticipate claim 9. Said moisture vapor permeable film is preferably a continuous elastic conformable film prepared from polyether, polyester polyurethane, or blends of polyurethane with incompatible polymers, such as polyolefins. The preferred films are polyurethanes under the band name Estane, such as Estane 5714F—see column 5, lines 55-67. Said moisture absorbing layer can have a moisture vapor transmission rate greater than $300\text{gm-}2\text{ }24\text{h-}1$ at $37\text{ }^{\circ}\text{C}$ and 100% to 10% relative humidity. Webster et al teaches said polyurethane incompatible films useable as backing layers are disclosed in GB patent 208172 (deemed to be incorporated in the disclosure Webster et al). Said polyurethane either with/without the incompatible polymer anticipates the polymers of claims 14, and 16-23. Wherein, the isocyanate linkages in the polyurethane are hard segments and the soft segments are the ester linkages, thus anticipating claims 19-20.

GB 2021872 teaches cold drawn films comprising a blend a polyurethane polymer and an incompatible polymer, wherein in said incompatible polymer may comprise other components, such as lubricants. Said incompatible polymer appears to anticipate applicant's non-activatable material in claims 24-25 and the non-elastomeric polymer in claim 10. Said polymer blend comprises from 40% to 90% of the polyurethane. This appears to anticipate claims 26-27. Said incompatible polymer may be a polyolefin, such as polystyrene that comprises up to 10% of a lubricant, such as glyceryl monostearate. Said polymer blends are mixed, extruded and stretched to form an elastomeric film. Said stretching is carried out at temperatures between $10\text{ }^{\circ}\text{C}$ and $45\text{ }^{\circ}\text{C}$ in a longitudinal or transverse direction. The film is stretched between 200 and 500 percent, wherein the

Art Unit: 1711

film has a recoverable elastic strain of at least 100% or more. This appears to read on applicant's draw or stretching ratio in claims 6-8.

Webster et al teaches the hydrophilic polymer layer can absorb at least 5%, up to 300 or 400% of their weight when fully hydrated and have a linear expansion of 15 to 55%. Therefore, the examiner contends that the moisture vapor permeable layer (backing layer) will expand when the foam layer absorbs exudate. Because the backing layer is the control mechanism for the escape of moisture vapor from the foam layer, said baking layer (moisture vapor permeable layer) it is deemed to be responsive to when exposed to moisture, i.e. the baking layer would have to expand as the foam layer expands in response to the absorption of exudates. This appears to anticipate claim 5 and the multi-layered structure of claim 9. The examiner deems the "moisture" teachings from the absorb exudates anticipated humidity because a wound in a closed environment produces heat from body temperature and moisture from the exudates to give a humid environment, which appears to be a moisture responsive material of claims 1-4. Therefore, the dressing of Webster et al is deemed to anticipate the claimed invention and thus the wound dressing of Webster et al should inherently exhibit a temperature change less than about 12 to 15 °C when subjected to a humid environment.

3. Claims 1-22, 24-28 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakakibara et al (5,112,903).

Sakakibara et al teaches articles molded from moisture shrinkable resins, which experience significantly smaller decrease in tensile strength during shrinking by absorbing moisture. Said articles do not require any heating for their shrinkage, but shrink in highly humid atmosphere (75% or higher) at room temperature. These appear to anticipate claims 2-4. Said articles are stretched. Said moisture shrinkable resins comprise a blend of a thermoplastic polymer with a hydrophilic synthetic polymer or a polysaccharide or a graft copolymer of the proceeding polymers. This appears to anticipate claims 10, 14-22, wherein the hydrophilic polymer is deemed to read on the moisture-absorbing polymer. Said article absorbs moisture and shrink at room temperature of not more than 50 °C. Said thermoplastic polymers can be selected from the group found in column 3, lines 8-42, wherein they can be used alone or in combinations, wherein thermoplastic polyurethane elastomers, thermoplastic rubbers,

Art Unit: 1711

nylons, styrene-butadienes are disclosed. These appear to anticipate claim 14. Said hydrophilic polymers can be chosen from four groups of polymer; (1) polymers having nonionic groups; (2) polymers having anionic groups; (3) polymers having cationic groups; and (4) polymers having amphoteric groups, wherein polyvinyl alcohols and derivatives thereof, ethylene-vinyl alcohol polymers are disclosed. The polymers of any groups can be used alone or in combinations, preferably said polymers comprise a structural unit including hydroxyl groups, ether groups or both. These are deemed to anticipate claims 15-22. Said polymer blend can comprise a ratio of 10:90 to 90:10 (thermoplastic to hydrophilic) within the composition. These ratios appear to anticipate claims 26-27. In addition, said resin composition can include extenders and additives as defined in column 15, lines 9-31. These appear to anticipate the non-activatable materials of claims 24-25.

Said polymer blend formed into a molded article, such as a film, sheet, tape, mesh, foam, fiber, or rod carried out by either by methods of stretch molding, such as stretch extrusion, blown film extrusion, or calendaring for use in such industries as meat packaging. Or, said method may be done by casting the blend into a film and then stretching said film. Said stretching can be done at heating at optimal temperatures for stretching, stretching the film biaxially, and then cooling the film. Per examples 6-7, Sakakibara et al teaches a stretch or draw ratio in the machine direction of 3.6 and in the transverse direction of 4.0 in example 6 and a machine direction of 3.2 and in the transverse direction of 3.6. This appears to anticipate claims 7-8. Sakakibara et al teaches that the molded articles can be in the form of multi-layered laminate films using extrusion laminate method followed by stretching using a multi-circular die. This appears to anticipate claim 9.

The inventions of claims 1-22 and 24-28 are anticipated by the reference, therefore the articles of Sakakibara et al would inherently exhibit at least a 20% to 50% reduction in modulus and exhibit a temperature change less than 12-15% when exposed to a humid environment, which anticipates claims 11-13 and 30-31.

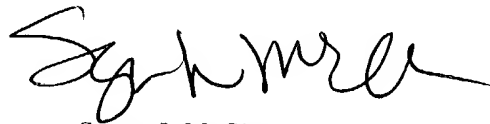
Conclusion

Art Unit: 1711

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sanza L McClendon

Examiner

Art Unit 1711

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